

REMARKS

This paper is filed responsive to the Office Action mailed June 25, 2010. Claims 16-46 are pending in the application. Claims 1-15 have been canceled. Applicants have amended claims 16-24, 29, 33 and 40-46 to more clearly define the invention and to positively recite the structural limitations of the claims. No new matter has been added.

Claims 16-19, 25-31, 40-43, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,298,992 (Burstein). Applicants traverse the rejection.

Claim 16 claims a knee joint prosthesis that includes a tibial component comprising an upper surface, a post extending from the upper surface in a direction extending generally upwardly from the upper surface, the post having a post bearing surface; and a femoral component comprising a medial condyle, a lateral condyle and a cam having a cam surface, wherein (i) the post bearing surface and the cam define a surface area of contact and (ii) the medial condyle and the lateral condyle act against the upper surface, and wherein the surface area of contact increases when the knee flexes to a flex angle greater than 120°.

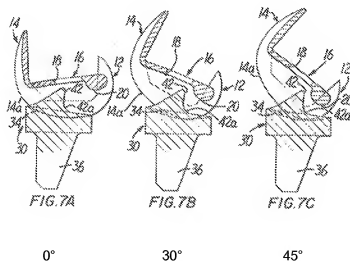
Claim 40 claims a knee joint prosthesis that includes a tibial component comprising an upper surface, a post extending from the upper surface in a direction extending generally upwardly from the upper surface, the post having a post bearing surface; a femoral component comprising a medial condyle, a lateral condyle and a cam having a cam surface, wherein (i) the post bearing surface and the cam surface define a surface area of contact and (ii) the medial condyle and the lateral condyle contact the upper surface, and wherein the surface area of contact increases when the knee is flexed to an angle greater than 120°.

Burstein does not anticipate independent claims 16 or 40. As the Examiner states, Burstein depicts a knee prosthesis having a femoral component and a tibial component. The femoral component includes a medial condyle, a lateral condyle and a cam having a cam surface. Further, the tibial component and the femoral component define a surface area of contact and the medial condyle and the lateral condyle act against the tibial bearing surface.

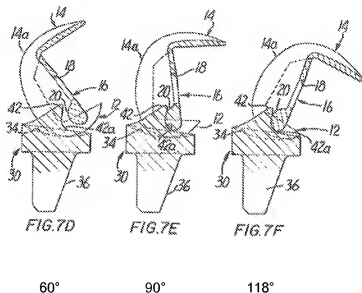
Burstein, however, does not describe that the "surface area of contact" between the post and the cam "increases when the knee flexes to a flex angle greater than 120°". Burstein fails to do so simply because it does not disclose flexing above 120°. As described in Burstein, "full flexion" occurs in the orientation depicted in Figure 7F. The Description of the Drawings section at column 3, lines 14-17 states:

FIGS. 7A to 7F are side cross-sectional views in generally schematic form showing the assembled components in various positions (corresponding to a range of leg articulation **from full extension to full flexion**).

Applicants submit the attached §1.132 Declaration of Richard Rowley at ¶ 6 ("Rowley Declaration") in support of patentability of the claimed inventions. It is well understood in the art that full extension represents a position of zero flexion or where the flex angle is zero. Thus, as Figure 7A corresponds to the full extension position of the Burstein implant, Figure 7A depicts a position where the flex angle is 0°. Rowley Declaration at ¶ 6. Based on this datum, Figures 7B and 7C depict the position of the femoral and tibial components oriented at 30 and 45 degrees, respectively. Rowley Declaration at ¶ 9.

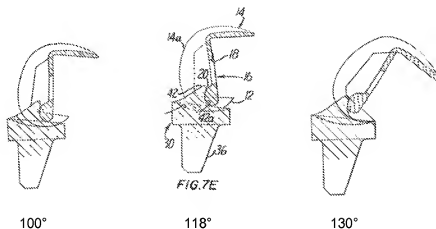


The final three figures of Burstein, Figures 7D-7F, depict the position of the femoral and tibial components oriented at 60, 90 and 118 degrees, respectively. Rowley Declaration at ¶ 9.



Thus, full flexion as defined by Burstein is 118 degrees. See Burstein, col. 3:14-17. As a result, Burstein cannot describe a surface area of contact defined by the tibial component and the cam that increases when the knee flexes to a flex angle greater than 120 degrees, as the components of Burstein do not flex above 118 degrees.

Burstein is not designed to flex above 118 degrees, but even if one were to force it to flex above 118 degrees (again at angles whereat Burstein is not designed to operate), Burstein still would not satisfy the claim element of both claims 16 and 40 that requires "the surface area of contact to increase when the knee flexes to a flex angle greater than 120°". The maximum surface area of contact defined by the tibial component and the cam of Burstein is achieved at approximately 100 degrees. See Rowley Declaration at ¶ 12 and the figure below, where the femoral component of Burstein has been rotated to show how the surfaces would engage at 100 degrees. At this position, the medial and lateral condyles are relatively fully engaged with the tibial component and the cam shown as element 20 (in the Burstein figures) is fully engaged with cam surface 42a of post 42.



As the femoral component rotates from 100° to 118° (as shown in Figure 7E of Burstein) to the above-depicted position at 130°, the cam 20 moves up the post 42 and the anterior aspects of the medial and lateral condyles lift off of the tibial component surface. As a result, as the knee flexes from 100 to 130 degrees, the cam moves up the post, and the surface area of contact between the cam and the post surface (of the tibial component) **decreases**. Thus, if the knee of Burstein is flexed beyond 120°, though not designed to do so, the area of contact between the post bearing surface and the cam would decrease, rather than increase. Rowley Declaration at ¶ 14. As a result, Burstein cannot be said to anticipate independent claims 16 or 40, both of which claim that the “surface area of contact” between the post and the cam “increases when the knee flexes to a flex angle greater than 120°”.

Accordingly, Burstein does not describe all of the elements of claims 16 or 40, and Applicants request that the rejection be withdrawn. Claims 17-19, 25-31, 41-43, and 46 depend from either claim 16 or 40 and thus are patentable for at least that reason, though Applicants reserve the right to argue patentability based on the dependent claims.

Claims 20-24, 32-39, 44 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burstein in view of U.S. Publication No. 2003/0023314 (“Burstein II”). Applicants traverse the rejection.

As described above, Burstein fails to teach at least one element of claims 16 and 40, the element that requires an increase in the surface area of contact when the knee flexes to a flex angle greater than 120° . Burstein II likewise does not teach that the surface area of contact between the post bearing surface and the cam surface increases as the knee flexes to a flex angle greater than 120° . There is no description of how the surface area of contact between the post bearing surface and the cam surface changes when the Burstein II knee is flexed above 120° .

Burstein II does, however, describes a knee implant that has an auxiliary pair of load bearing surfaces that under normal mechanical operation do not transmit loads. The auxiliary load bearing surfaces transmit loads only where the knee implant sees one of two conditions: 1) where the knee is flexed to a high flexion angle (greater than 120°) and then rotated in the varus/valgus direction; or 2) where wear occurs in the medial or lateral condyle to an appreciable degree. Burstein II, col 1:52 – col 2:11. The auxiliary pair of load bearing surfaces are described as the cam follower 20 and the surface 44. Burstein II, col 3:61-62.

Tibial component 2 is further provided with a surface 44 located in the posterior region of the component, adjacent the stabilizing post 42 and adjacent the cam surface 42a. The surface 44 is centered between the tibial condyles 32 and 34. Sidewalls 46 define the lateral edges of the surface 44. Surface 44 slopes upward from a lower region adjacent the cam surface 42a to an upper region located at the edge 30a' of the posterior surface of the tibial component.

Burstein II, col 3:53-60. As discussed in the above paragraph, and referring below to Figures 4 and 5B of Burstein II,

FIG. 4

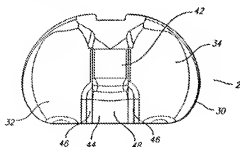
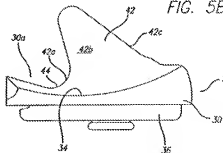


FIG. 5B



surface 44 is depicted as being located on the tibial component “***adjacent the stabilizing post 42 and adjacent the cam surface 42a***”. Burstein II, col 3:54-55. Specifically, surface 44 is located posterior to stabilizer post 42. As a result, any contact between the cam follower 20 (located on the femoral component) of Burstein II and the surface 44 under the specific conditions noted above at 1) and 2), cannot increase the surface area of contact between the post bearing surface and the cam surface increases as the knee flexes to a flex angle greater than 120° as neither of the pair of load bearing auxiliary surfaces—surface 44 and cam follower 20—are located on the post bearing surface. Cam follower 20 is located on the femoral component (see Figure 2), and surface 44 is located adjacent the post bearing surface. Burstein Figures 4 and 5B above. Applicants submit that neither Burstein nor Burstein II describe each of the elements of claims 16 and 40, and therefore cannot anticipate independent claims 16 or 40.

Further, Applicants submit that one skilled in the art would not be motivated to combine Burstein and Burstein II, as Burstein is not designed to operate at flexion angles above 118 degrees, while Burstein II appears to contemplate operating at angles greater than 120 degrees. In the event that one did combine the two reference, however, as discussed above, the combination of the two would still fail to describe the claimed invention of claims 16 or 40. As described above, in the Burstein design, the surface area of contact between the post bearing surface and the cam surface decreases as the knee flexes to a flex angle greater than 120°. In Burstein II, there is no description of how the surface area of contact (defined in claims 16 and 40 as being between the post bearing surface and the cam) changes when the Burstein II knee is flexed above 120°. Applicants seek withdrawal of the rejections.

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Serial No. 10/566147

Please charge any fee associated with the prosecution of this application to Deposit Account No. 10-0750. Applicants submit that the application is presently in condition for allowance and request favorable reconsideration and early notice of allowance. If it would speed prosecution, the Examiner is encouraged to contact the undersigned attorney by telephone.

Respectfully submitted,

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